10 510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K022493

10.1 Submitter's Identification:

OCT 11 2002

Body Clock Health Care Ltd
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Contact: Jonathan Bash
Date Prepared: July 23rd 2002

10.2 Name of Device:

Proprietary Name:
EMS 400

Common or Usual Name:
Powered Muscle Stimulator.

Classification Name:
Powered Muscle Stimulator.

10.3 Predicate Device Information:

The EMS 400 is substantially equivalent to the EMS 400 **(K913272)**

10.4 Device Description:

The EMS 400 a dual channel EMS (Powered Muscle Stimulator) unit. It is identical to the Altoona EMS 400 (**K913272**). It has two intensity (amplitude) dials for each channel, placed on the front of the unit. Directly below the left-hand-side intensity dial is a pulse rate dial, which sets the pulse rate for both channels. Below the right-hand dial is a timer dial, which controls the time of each cycle when cycle or reciprocal mode is used. If the dial is set to 0, the unit provides a constant mode.

10.5 Intended Use:

- Relax muscle spasms
- Prevent or retard disuse atrophy
- Maintain or increase range of motion
- Increase local blood circulation
- Re-educate muscle
- Immediate post-surgical stimulation of calf muscle to prevent venous thrombosis

10.6 Technological Comparison to Predicate Devices:

The EMS 400 has basic technological characteristics that are substantially equivalent to the predicate devices.

This unit uses dials to change the settings. It also uses shrouded patient cable connectors to comply with the FDA's Final Rule "Medical Devices: Establishment of Performance Standards for Electrode Lead Wires and Patient Cables."

10.7 Non-clinical Testing:

All Units are fully CE marked i.e. compliant with **EEC Directive 93/42/EEC Annex V**, classified as "Internally powered Equipment Type BF. They are intended for continuous operation."
ISO 9002
ISO 13488
EN 46002
EN 60601-1-2:1993 (**EEC Directive 89/336/EEC**)

10.8 Clinical Testing:

Not Applicable as there are no new or innovative aspects that have been introduced.

10.9 Conclusions:

The EMS 400 has the same intended use and same technical characteristics as the EMS 400 **(K913272)**

The information supplied in this 510(k) illustrate that the device does not pose any new questions of safety and effectiveness. EMS 400 is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2002

Mrs. Rashelle Preston
Body Clock Health Care Limited
108 George Lane
South Woodford
London E18 1AD
United Kingdom

Re: K022493
Trade/Device Name: EMS 400
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: July 23, 2002
Received: July 29, 2002
Amended: July 29, August 16, and September 4, 2002

Dear Mrs. Preston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic

product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k)

premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

8 Statement of Indications For Use

510(k) Number (if known): K022493

Device Name: Body Clock EMS 400

Indications for Use: The Body Clock EMS 400 is an electrically powered device intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area. It is indicated for the following:

1. Relaxation of muscle spasms;
2. Prevention or retardation of disuse atrophy;
3. Increasing local blood circulation;
4. Muscle re-education;
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and
6. Maintaining or increasing range of motion.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices
510(k) Number K022493

Prescription Use X
(Per 21 CFR 801.109)